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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,631	09/20/2001	Oleg Mirochnitchenko	266/171	4309

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/960,631	MIROCHNITCHENKO ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-8**, drawn to a *method for producing a polypeptide* comprising isolated polynucleotides encoding the polypeptide of the SEQ ID NO: 2 amino acid sequence comprising isolated nucleic acids of the SEQ ID NO: 1 and SEQ ID NO: 3 polynucleotides, expression vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

II. Claim **9**, drawn to an isolated *polypeptide* comprising the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 300, for example.

III. Claim **10**, drawn to an *antibody* immunospecific for the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 387.1, for example.

IV. Claims **11-18**, drawn to a *method for producing a polypeptide* comprising an isolated polynucleotide encoding the polypeptide of the SEQ ID NO: 5 amino acid sequence comprising isolated nucleic acid of the SEQ ID NO: 4 polynucleotide, expression vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

V. Claim **19**, drawn to an isolated *polypeptide* comprising the amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 300, for example.

VI. Claim **20**, drawn to an *antibody* immunospecific for the amino acid sequence of SEQ ID NO: 5, classified in class 530, subclass 387.1, for example.

VII. Claims **21-28**, drawn to a *method for producing a polypeptide* comprising an isolated polynucleotide encoding the polypeptide of the SEQ ID NO: 7 amino acid sequence comprising isolated nucleic acid of the SEQ ID NO: 6 polynucleotide, expression vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

VIII. Claim **29**, drawn to an isolated *polypeptide* comprising the amino acid sequence of SEQ ID NO: 7, classified in class 530, subclass 300, for example.

IX. Claim **30**, drawn to an *antibody* immunospecific for the amino acid sequence of SEQ ID NO: 7, classified in class 530, subclass 387.1, for example.

X. Claims **31-38**, drawn to a *method for producing a polypeptide* comprising an isolated polynucleotides encoding the polypeptide of the SEQ ID NO: 9 amino acid sequence comprising isolated nucleic acid of the SEQ ID NO: 8 polynucleotide, expression vectors, and host cells comprising same, classified in class 435, subclass 69.1, for example.

XI. Claim **39**, drawn to an isolated *polypeptide* comprising the amino acid sequence of SEQ ID NO: 9, classified in class 530, subclass 300, for example.

XII. Claim **40**, drawn to an *antibody* immunospecific for the amino acid sequence of SEQ ID NO: 9, classified in class 530, subclass 387.1, for example.

XIII. Claim **41**, drawn to an isolated *polynucleotide* encoding a soluble protein that bind IAP, classified in class 530, subclass 300, for example.

XIV. Claims **42 (in part), 43-50, 55-58, 62-78,** and **83** drawn to a *method of detecting organ failure* comprising measuring an IAP mRNA level, classified in class 435, subclass 6, for example.

XV. Claims **42 (in part), 51-54,** drawn to a *method of detecting organ failure* comprising measuring an IAP protein level, classified in class 435, subclass 7.1, for example.

XVI. Claims **59** and **79**, drawn to a *method of preventing organ failure* in a mammal comprising taking a preventative measure, classification dependent upon method steps.

XVII. Claims **60-61** and **80-81**, drawn to a *method of determining prognosis of a patient* following a medical procedure, classification dependent upon method steps.

XVIII. Claim **82 (in part)**, drawn to a *method of detecting a condition* that is related to an increased inflammatory response in mammal comprising measuring a level of an IPA mRNA, classified in class 435, subclass 6, for example.

XIX. Claim **82 (in part)**, drawn to a *method of detecting a condition* that is related to an increased inflammatory response in mammal comprising measuring a level of an IPA protein, classified in class 435, subclass 7.1, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions

for the following reasons: Inventions I, IV, VII, X, XIV, XV, XVI, XVII, XVIII, and XIX are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of producing a polypeptide comprising the amino acid sequence of SEQ ID NO: 2, which is not required by any of the other Inventions. Invention IV requires search and consideration of producing a polypeptide comprising the amino acid sequence of SEQ ID NO: 5, which is not required by any of the other Inventions. Invention VII requires search and consideration of producing a polypeptide comprising the amino acid sequence of SEQ ID NO: 7, which is not required by any of the other Inventions. Invention X requires search and consideration of producing a polypeptide comprising the amino acid sequence of SEQ ID NO: 9, which is not required by any of the other Inventions. Invention XIV requires search and consideration of detecting organ failure comprising measuring an IAP mRNA level, which is not required by any of the other Inventions. Invention XV requires search and consideration of detecting organ failure comprising measuring an IAP protein level, which is not required by any of the other Inventions. Invention XVI requires search and consideration of preventing organ failure, which is not required by any of the other Inventions. Invention XVII requires search and consideration of determining prognosis of a patient, which is not required by any of the other Inventions. Invention XVIII requires search and consideration of detecting a condition that is related to an increased inflammatory response in mammal via mRNA level measurement, which is not required by any of the other Inventions. Invention XIX requires search and consideration of detecting a condition that is related to an increased inflammatory response in mammal via protein level measurement, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, III, V, VI, VIII, IX, XI, XII, and XIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

5. The polypeptide of Invention II can be prepared by processes which are materially different from antibody of Invention III, such as by chemical synthesis. The polypeptide of Invention II is independent and distinct from the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention VIII, the antibody of Invention IX, the polypeptide of Invention XI, the antibody of Invention XII, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the polypeptide of Invention II.

6. The antibody of Invention III can be prepared by processes which are materially different from polypeptide of Invention II, such as by chemical synthesis, recombinant expression, and purification from natural sources. The antibody of Invention III is independent and distinct from the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention VIII, the antibody of Invention IX, the polypeptide of Invention XI, the antibody of Invention XII, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the antibody of Invention III.

7. The polypeptide of Invention V can be prepared by processes which are materially different from antibody of Invention VI, such as by chemical synthesis. The polypeptide of Invention V is independent and distinct from the polypeptide of Invention II, the antibody of

Invention III, the polypeptide of Invention VIII, the antibody of Invention IX, the polypeptide of Invention XI, the antibody of Invention XII, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the polypeptide of Invention V.

8. The antibody of Invention VI can be prepared by processes which are materially different from polypeptide of Invention V, such as by chemical synthesis, recombinant expression, and purification from natural sources. The antibody of Invention VI is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention VIII, the antibody of Invention IX, the polypeptide of Invention XI, the antibody of Invention XII, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the antibody of Invention VI.

9. The polypeptide of Invention VIII can be prepared by processes which are materially different from antibody of Invention IX, such as by chemical synthesis. The polypeptide of Invention VIII is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention XI, the antibody of Invention XII, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the polypeptide of Invention VIII.

10. The antibody of Invention IX can be prepared by processes which are materially different from polypeptide of Invention VIII, such as by chemical synthesis, recombinant expression, and purification from natural sources. The antibody of Invention IX is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention XI, the antibody of Invention XII, and the

polynucleotide of Invention XIII because none of these Inventions is required to make or use the antibody of Invention IX.

11. The polypeptide of Invention XI can be prepared by processes which are materially different from antibody of Invention XII, such as by chemical synthesis. The polypeptide of Invention XI is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention VIII, the antibody of Invention IX, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the polypeptide of Invention XI.

12. The antibody of Invention XII can be prepared by processes which are materially different from polypeptide of Invention XI, such as by chemical synthesis, recombinant expression, and purification from natural sources. The antibody of Invention XII is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention VIII, the antibody of Invention IX, and the polynucleotide of Invention XIII because none of these Inventions is required to make or use the antibody of Invention XII.

13. The polynucleotide of Invention XIII is independent and distinct from the polypeptide of Invention II, the antibody of Invention III, the polypeptide of Invention V, the antibody of Invention VI, the polypeptide of Invention VIII, the antibody of Invention IX, the polypeptide of Invention XI, and the antibody of Invention XII because none of these Inventions is required to make or use the polynucleotide of Invention XIII.

14. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention II can be prepared by processes which are materially different from recombinant DNA expression of Invention I, such as by chemical synthesis, or by isolation and purification from natural sources.

15. Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention V can be prepared by processes which are materially different from recombinant DNA expression of Invention IV, such as by chemical synthesis, or by isolation and purification from natural sources.

16. Inventions VII and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention VIII can be prepared by processes which are materially different from recombinant DNA expression of Invention VII, such as by chemical synthesis, or by isolation and purification from natural sources.

17. Inventions X and XI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be

made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention XI can be prepared by processes which are materially different from recombinant DNA expression of Invention X, such as by chemical synthesis, or by isolation and purification from natural sources.

18. Inventions II and each of XV and XIX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention II can be used in materially different methods other than each of Inventions XV and XIX, such as making the antibody of Invention III.

19. Inventions V and each of XV and XIX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention V can be used in materially different methods other than each of Inventions XV and XIX, such as making the antibody of Invention VI.

20. Inventions VIII and each of XV and XIX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention VIII can be used in materially different methods other than each of Inventions XV and XIX, such as making the antibody of Invention IX.

21. Inventions XI and each of XV and XIX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention XI can be used in materially different methods other than each of Inventions XV and XIX, such as making the antibody of Invention XII.

22. Inventions III and each of XV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used in materially different methods, such as to obtain the polypeptide of Invention II.

23. Inventions VI and each of XV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention VI can be used in materially different methods, such as to obtain the polypeptide of Invention V.

24. Inventions IX and each of XV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IX can be used in materially different methods, such as to obtain the polypeptide of Invention VIII.

25. Inventions XII and each of XV and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention XII can be used in materially different methods, such as to obtain the polypeptide of Invention XI.

26. Inventions II and each of IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IV, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *polypeptide* of Invention II.

27. Inventions V and each of I, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case the different inventions of Inventions V and each of I, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *polypeptide* of Invention V.

28. Inventions VIII and each of I, IV, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and each of I, IV, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *polypeptide* of Invention VIII.

29. Inventions XI and each of I, IV, VII, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XI and each of I, IV, VII, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, VII, XIV, XVI, XVII, and XVIII do not recite the use or production of the *polypeptide* of Invention XI.

30. Inventions III and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each

of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention III.

31. Inventions VI and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VI and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention VI.

32. Inventions IX and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IX and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention IX.

33. Inventions XII and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XII and each of I, IV, VII, X, XIV, XVI, XVII, and XVIII are unrelated product and methods, wherein each is

not required, one for another. For example, the claimed methods of Inventions I, IV, VII, X, XIV, XVI, XVII, and XVIII do not recite the use or production of the *antibody* of Invention XII.

34. Inventions XIII and each of I, IV, VII, X, XIV, XV, XVI, XVII, XVIII, and XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions XIII and each of I, IV, VII, X, XIV, XV, XVI, XVII, XVIII, and XIX are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, VII, X, XIV, XV, XVI, XVII, XVIII, and XIX do not recite the use or production of the *polynucleotide* of Invention XIII.

35. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

36. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

37. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

38. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

39. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

40. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Summary

41. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Lorraine Spector, Ph.D.** whose telephone number is **(571) 272-0893**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
June 21, 2004

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER